

**STAGE 2 - RESEARCH ETHICS APPROVAL FORM**

All research carried out by students and staff at the University must receive ethical approval before any data collection commences.

**Notes**

* Applicants complete the Risk Checklist and Stage 1 - Research Ethics Approval Form prior to completing this Stage 2 - Research Ethics Approval Form. Following completion of the Risk Checklist and Stage 1 - Research Ethics Approval Form, if your research study was provisionally classified as Risk Category 2 or 3, you need to complete this form.
* Full details of the project are to be provided in this Stage 2. Where a question in the Risk Checklist was answered YES, please ensure that specific details are included in the appropriate box below.
* If a question does not apply to your project, insert ‘Not applicable’ or N/A.
* Help is provided for each question. Further help can be found in the Research Ethics Procedures document.
* You navigate through the form by using the tab keys. If you prefer to complete a normal Word document, you can unlock the form by selecting the ‘Restrict Editing’ button on the Developer tab, then click on ‘Stop Protection’. The boxes should expand to allow space for your text.
* Spellchecking is not available in Word forms, so you may find it helpful to prepare your responses in a Word document and then copy these to this form.
* Ensure the form is completed in sufficient detail to allow the reviewer to judge the ethical issues raised by the study. Remember that the reviewer will be considering the following questions when reviewing your application in order to be able to give ethical approval:
  + is it ethical to conduct the research project and is the proposed method of investigation appropriate, thorough and ethical?
  + does the research project meet the requirements of the relevant Research Ethics Principles (Research Ethics Policy A2.4)?

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| **TO BE COMPLETED FOR PROJECTS IN RISK CATEGORY 2 AND 3** | |
| **Your name** | Soya Shrestha |
| **Project title** | Smart Vitals: A Portable Health Monitoring System |

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| **1** | **Project Overview** |
| **Please give a brief overview of your study, including a summary of your aims and objectives.**  Help: Describe the purpose of the research and what question(s) the project should answer. | |
| The Smart Vitals: A Portable Health Monitoring System project aims to design and develop a portable, IoT-based health monitoring device capable of tracking key vital signs, including heart rate, SpO₂ (oxygen saturation), ECG, blood pressure, and body temperature. The system will provide users with real-time access to their health data through an OLED display for immediate feedback, as well as a mobile application for remote monitoring. By integrating advanced sensors such as the MAX30102 for SpO₂ and heart rate, the AD8232 for ECG, and a temperature sensor, the device will ensure accurate and timely readings.  The primary objective of this project is to offer an accessible, reliable, and portable solution for ongoing health monitoring, making it easier for individuals to track their vital signs and detect potential health issues early. With the added capability of real-time alerts sent through the mobile app, caregivers and users will be notified of abnormal readings, ensuring that timely interventions can be made when necessary.  Ultimately, the project aims to assess the effectiveness of an IoT-driven, portable health monitoring system in providing continuous health insights and enabling proactive healthcare management, especially in situations where immediate medical attention is needed. | |

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| **2** | **Methodology** |
| **Please give a description of your methodology, including any data collection and analysis methods.**  Help: Give an outline of your study here. If the project is complex, you can also submit your research proposal/protocol (no more than 2-3 A4 sides) if this would help the reviewer’s understanding of the project. Include details of your (or your Research Supervisor’s) appropriate skills and qualifications to carry out this research. | |
| SpO₂ sensors, EGC sensors, temperature sensors, and Arduino board, are selected based on their performance and precision. The sensors are embedded in Arduino and evaluated for different measurements, for real-time access including OLED display with graphics.  Real time health readings are provided to the users through a flutter-based mobile application whenever any irregularities are detected. It also provides data security through an encrypted communication system ensuring the users' privacy**.**  The sensors’ reliability and precision would be validated by contrasting the readings with the medical devices. The project would implement Agile methodology, by dividing the development process into iterative phases, focusing on particular milestones, including sensor configuration and mobile app development. In order to track the progress, Gnatt chart and Timeline would be used. | |

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| **3** | **Main Ethical Considerations** |
| **Please give a brief description of the main ethical considerations involved in the study.**  Help: All research projects will have ethical issues, and you will be asked later in the process on recruitment, voluntary participation and the right to withdraw, but highlight here the main ethical considerations for your study (which may concern, e.g., the type of participants, the sensitive nature of the study, the data collection process, a lone researcher carrying out research off-campus, security-sensitive research) and advise how you will address the main issues. If the project is funded, give details here, and whether there are any potential conflicts of interest involved in the study. | |
| The main ethical considerations for the Smart Vitals project include ensuring the privacy and confidentiality of participants' health data, obtaining informed consent, and ensuring voluntary participation with the right to withdraw. Data will be anonymized, securely stored, and accessible only to authorized personnel. Participants will be fully informed about data collection, storage, and potential risks. The research will be conducted within the personal premises of the participants. The project is self-funded, not involving any external financial aid or conflicts of interest involved in the study. | |

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| **4** | **Human Participants** |
| **If your study includes Human Participants (or their data), please give a description of who will be included.**  Help:   * Please note this should include sample size/number of participants, whether the project will focus on any particular groups/individuals, if it will include any at risk or vulnerable participants, participants aged 16 years or under, etc. Please also specify your rationale for including / excluding groups of participants. * If the research involves secondary data not in the public domain, give details in this section. | |
| For my project, Smart Vitals, it is essential to have human participants for testing phase, which will allow me to get more precise health data. I do not intend to include a huge number of participants as I will be doing most of the testing within personal premises, possibly after performing various activities to ensure that the readings from my sensors are able to get accurate data in various conditions. So, I will be including participants no more than 5.  No at-risk or vulnerable participants, including those under 16, will be involved in this study to avoid ethical and safety concerns. The inclusion criteria focus on adults who can provide informed consent and actively participate in device testing.  This research does not involve the use of any secondary data that is not in the public domain. All data collected will be primary, gathered directly from participants through the Smart Vitals health monitoring device during testing. Data will be used solely for the purpose of evaluating the device’s accuracy and performance and will be handled with strict confidentiality and security measures. | |

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| **5** | **Recruitment, Voluntary Participation, Consent and Right to Withdraw** |
| **If your study includes Human Participants, please give a brief description of the recruitment process, how you will ensure voluntary participation, if (and how) informed consent will be obtained prior to participants taking part in the study, and the right of withdrawal from the research process.**  Help:   * This should include clear information on how participants will be identified, approached and recruited; whether the study will include any covert research or deliberate deception; whether help is required from a third party/ gatekeeper to access participants; what information you will give participants, etc. * If expenses or any incentives are to be offered to participants, give full details. * If your research involves students, colleagues and/or other employees then you must specify the rationale for this and how you will address issues of coercion or feelings of obligation. * Regarding withdrawal from the study, discuss the different stages/dates a participant could withdraw or withdraw their data, and how they could do this. | |
| Participants will be recruited voluntarily where the project’s risks, benefits, scope and objectives will be clearly stated for the participants to make decision for research and testing. No third-party or gatekeeper involvement will be required for access to participants, with no expenses or any incentives are to be offered to participants.  Participants will have the right to withdraw from the study at any stage without any obligation to provide a reason. They will also have the option to withdraw their data from the study up to a specified date before data analysis begins. If the participants want to withdrawal their data a prior email will be much appreciated, so that other participants can be involved. | |

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| **6** | **Risks and Benefits** |
| **Please give a brief description of how, when and where the research will take place and whether there are any risks and/or benefits involved.**  Help:   * This should include information on what participants will be required to do, the rationale for this and the level of risk involved. * When considering risks, please refer to risks to the participants (e.g., for research in sensitive areas), the researcher, any other parties to the research; and also any health and safety issues for anyone involved (e.g., for lone researchers carrying out fieldwork). * If participants will be exposed to ionising radiation, separate approval documentation must be submitted with this application. | |
| The testing will be held begin within different time phrase, primarily conducted within the participants premises, where the device can be safely tested. They will follow simple instructions, like placing their finger on the MAX30102 sensor, attaching ECG patches to the chest area, and positioning the temperature sensor on the body for accurate readings.  There will be minimal risks involved, which may be due to slightly discomfort from the ECG patches. Proper placement instruction and care will be given to make sure such discomfort are minimal. There is no use of ionizing radiation or invasive procedures in this research.  The benefit of this research will be result in the development of a portable health monitoring device that can provide real-time data and timely alerts for medical interventions. This can be useful to individuals to manage health conditions. It reduces the need for frequent hospital visits and costly medical checkups by enabling users to monitor their vital signs conveniently from home.  Additionally, this portable device is especially beneficial for adventure enthusiasts, travellers, and outdoor lovers who may not always have easy access to medical facilities, ensuring they can keep track of their health status. | |

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| **7** | **Personal Data, Anonymity and Confidentiality** |
| **Please specify what type of information/data will be collected/analysed and the source(s). In addition, specify if and how you will ensure the anonymity of participants and keep information confidential.**  Help: This should include information on whether you are collecting new information/data or using that that is already in the public domain; whether the data you are using includes personal details; how the data will be processed and stored; who will have access to it; how and when it will be destroyed; the Data Protection requirements for any sensitive personal data, etc. In addition, include whether there may be any requirements for disclosure of information to other parties due to professional practice or legal reasons. If there are limits to confidentiality, explain clearly how the participants would be advised about these limits and possible outcomes. | |
| The Smart Vitals: A Portable Health Monitoring System project will collect personal health data such as heart rate, SpO₂ levels, blood pressure, and body temperature. This data will be securely stored via encryption and accessible only by authorized personnel (researchers). Anonymity will be maintained and data will be processed locally, all the logs will be deleted after the completion of the project. Participants will be informed about any limitations to confidentiality. | |

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| **8** | **Reporting and Dissemination** |
| **Please give details of the planned dissemination and specify if the findings from the research will be published and whether any permission is required for this.**  Help: This should include information on the methods of dissemination (e.g., dissertation/thesis) and/or what will be published and where (research papers, conference presentations). Specify if any permission is needed (e.g., from participants, clients, gatekeepers, etc.) prior to publication, and whether there are any potential issues relating to Intellectual Property Rights when creating or using materials. | |
| The findings from this research will be primarily disseminated through the final report submitted to The British College as part of the BSc Computing degree Production Project module.  As of now, I have no intention of publishing the finding of the research. If I were to publish the project, permission will be obtained from participants to use their anonymized data, ensuring confidentiality and ethical standards are maintained. No external permissions from gatekeepers are needed, and there are no known issues related to Intellectual Property Rights, as all materials and designs for the Smart Vitals system are original or openly accessible. | |

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| **9** | **Location of research** |
| **Will the research take place outside of the country where you are enrolled as a student, or for staff, outside of the UK?** | |
| **YES ☐ NO Checkmark If yes, give details below.**  Help: If yes, please specify where the research will take place and what will be involved. Research must comply with the laws of the country where it is taking place and also comply with local Data Protection and Intellectual Property legislation: you must confirm that your research is compliant with local requirements and how you have ascertained this. Advise if the project requires ethical approval in-country and how this has been ascertained. If approval is required, a copy of this should be included in the application or details of the process of how it will be obtained. Please make reference to insurance and indemnity cover for the project where relevant. | |
| N/A | |

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| **10** | **Collaborative Projects** |
| **Is the research is a collaborative project (i.e., it involves more than one institution)?** | |
| **YES ☐ NO Checkmark If yes, give details below.**  Help: If yes, please specify the other institutions involved and if ethical approval needs to be / has been given by them. Please also specify what procedures have been put in place to ensure ethical compliance from all partners. | |
| N/A | |

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| **11** | **Any other permission or external ethical approval required to undertake the project** |
| **Please specify if the project requires any other ethical approval or permissions not mentioned previously in this application and how and when these will be obtained.**  Help:   * Other permissions: ethical approval does not give the right of access to the University’s students, staff or the use of University premises to carry out research, and you may need to contact an appropriate University gatekeeper for agreement to approach potential participants or for the use of premises, so please give details. * Gatekeepers: permission of a gatekeeper for initial access to participants may be required or to carry out data collection on their premises. * If your project requires approval from an external ethics committee, this should normally be obtained prior to submitting this application. * If a Disclosure and Barring Service check is required due to the specific participant group, give details. * Regarding insurance and indemnity cover, some projects will require individual confirmation of cover. See the Research Ethics Procedures document for more details. | |
| This project does not require any additional ethical approvals or permissions beyond what has been outlined in this application. The study will involve voluntary participation from individuals providing their health data through the Smart Vitals device, with informed consent obtained beforehand. No external ethics committee approval or gatekeeper permissions are necessary, as the data collection will not take place on third-party premises, nor will it involve at-risk or vulnerable groups. Additionally, no Disclosure and Barring Service check is required, and the project activities fall within the standard scope of ethical research practices. | |

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| **FOR PROJECTS INVOLVING RISK CATEGORY 2 AND 3: DECLARATION AND SIGNATURE/S** | | | |
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| **APPLICANT (STUDENT/STAFF MEMBER/RESEARCHER)** | | | |
| *I confirm that I will undertake this project as detailed in stage one and stage two of the application. I understand that I must abide by the terms of this approval and that I may not make any substantial amendments to the project without further approval. I understand that research with human participants or their data must not commence without ethical approval.* | | | |
| I have read an appropriate professional or learned society code of ethical practice: | | Yes **Checkmark** N/A☐ | |
| Where applicable, give the name of the professional or learned society: | |  | |
| *Signed* |  | *Date* | 28th February |

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| **RESEARCH SUPERVISOR/DIRECTOR OF STUDIES RECOMMENDATION FOR STUDENT PROJECTS** | | | | | |
| *I confirm that I have read stage one and stage two of the application. The project is viable and the student has appropriate skills to undertake the project. Where applicable, the Participant Information Sheet and recruitment procedures for obtaining informed consent are appropriate and the ethical issues arising from the project have been addressed in the application. I understand that research with human participants must not commence without ethical approval. I recommend this project for approval.* | | | | | |
| *Name* | Rohit Raj Pandey | *Signed* |  | *Date* | 2nd March |

**Local Research Ethics Co-ordinators**

*Please complete EITHER* ***A*** *(giving ethical approval for the project) OR* ***B*** *(recommending the project to the School level group for approval)*

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| **A** | **LOCAL RESEARCH ETHICS CO-ORDINATOR APPROVAL**  *For projects approved by the Local Research Ethics Co-ordinator* | | | | | |
| *I confirm ethical approval for this project* | | | | | | |
| *LREC Name* | |  | *Signed* |  | *Date* |  |

**OR**

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| **B** | **LOCAL RESEARCH ETHICS CO-ORDINATOR’S RECOMMENDATION FOR SCHOOL APPROVAL**  *For projects that require School level approval* | | | | | |
| *I recommend this project for consideration at school level. It cannot be approved at local level due to the following reason(s)* | | | | | | |
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| *LREC Name* | |  | *Signed* |  | *Date* |  |

**School level group**

*For projects approved at School level please complete the box below.*

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| **PROJECTS APPROVED BY THE SCHOOL LEVEL GROUP** | | | | | |
| *I confirm that this project was considered by the School level group and has received ethical approval* | | | | | |
| *Group Lead* |  | *Signed* |  | *Date* |  |

**OR**

**University Research Ethics Sub-Committee**

*For projects approved by URESC please complete the box below.*

*Projects involving security-sensitive research do not need supervisor/LREC approval prior to being considered by the Chair of URESC.*

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| **PROJECTS APPROVED BY THE RESEARCH ETHICS SUB-COMMITTEE** | | | | | |
| *I confirm that this project was considered by the Research Ethics Sub-committee and has received ethical approval* | | | | | |
| *Chair* |  | *Signed* |  | *Date* |  |

*This form will be retained for the purposes of quality assurance of compliance and audit for THREE years*

**SUPPORTING DOCUMENTATION: what to submit with the application**

For projects involving human participants, you must submit, where appropriate, the Participant Information Sheet/s and consent form/s. You must also submit every communication a participant will see or receive. Failure to do so will cause delays to the application.

Below is a checklist reminder of what could be submitted, depending on the research project. Please tick the appropriate boxes for each attachment or give details of the document at the end of the checklist.

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| **SUBMISSION CHECKLIST** | **Tick box** |
| RISK CHECKLIST AND STAGE 1 – RESEARCH ETHICS APPROVAL FORM | **Checkmark** |
| STAGE 2 – RESEARCH ETHICS APPROVAL FORM | **Checkmark** |
| Participant Information Sheet(s) | **☐** |
| Consent Form(s) | **☐** |
| Assent Form (usually for children participants) | **☐** |
| Recruitment documents  *eg, posters, flyers, advertisements, email invitations, letters, web pages if online research* | **☐** |
| Measures to be used  *eg, questionnaires, surveys, interview schedules, psychological tests* | **☐** |
| Screening questionnaire | **☐** |
| Letters/communications to and from gatekeepers/third parties | **☐** |
| Evidence of any other approvals or permissions  *eg, NHS research ethics approval, in-country approval* | **☐** |
| Research proposal/protocol (no more than 2-3 A4 pages)  *It is not a requirement that this is included, however, if this would help the understanding of a complex project by the reviewer(s), please include* | **☐** |
| Risk assessment form  *Some projects may require a risk assessment form: see the Procedures document for details (eg, projects involving a physical intervention, collecting data off-campus)* | **☐** |
| Approval documentation for projects involving ionising radiation | **☐** |
| Confirmation of insurance and indemnity cover where relevant  *Some projects need to be referred to the Insurance & Risk Officer: see the Procedures document* | **☐** |
| Security-sensitive research form | **☐** |
| Other: give details here: | **☐** |
|  | **☐** |

**SUBMITTING YOUR FORMS**

* Students: email the typed forms (stage one and stage two) and supporting documentation to your Research Supervisor or Director of Studies.
* Staff: email the typed forms (stage one and stage two) and supporting documentation to your Local Research Ethics Co-ordinator.
* Security-sensitive research: the stage one form (and stage two form if applicable) should be submitted directly to the URESC Chair, Professor Karl Spracklen, [k.spracklen@leedsbeckett.ac.uk](mailto:k.spracklen@leedsbeckett.ac.uk) and include the Security-sensitive research form, available from the Research Ethics web page.